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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2016-N-0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of eight new animal drug applications (NADAs) at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product Name	21 CFR Section
012-548[1]	TYLOSIN (tylosin phosphate) / HYGROMIX (hygromycin B)	558.274
013-162[1]	TYLAN TM (tylosin phosphate) Type A medicated article	558.625
013-388[1]	TYLAN (tylosin phosphate) / HYGROMIX (hygromycin B) Premix	558.274
015-166[1]	TYLAN TM (tylosin phosphate) Type A medicated article	558.625
127-507[1]	TYLAN 5 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 10 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 20 SULFA-G (tylosin phosphate and sulfamethazine), TYLAN 40 SULFA-G (tylosin phosphate and sulfamethazine)	558.630
141-164[1]	TYLAN (tylosin phosphate) / COBAN (monensin)	558.355
141-170[1]	TYLAN (tylosin phosphate) / MONTEBAN (narasin)	558.363
141-198[1]	TYLAN TM (tylosin phosphate) / BIO-COX (salinomycin)	558.550

[1]These NADAs were identified as being affected by guidance for industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209," December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 012-548, 013-162, 013-388, 015-166, 127-507, 141-164, 141-170, and 141-198, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 8, 2016.

Tracey H. Forfa,

Deputy Director,

Center for Veterinary Medicine.

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